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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,279	09/30/2002	Jeffrey C. Leung	2284.40533	5693
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ANGIOTECH 1633 Westlake Avenue N., Ste. 400 Seattle, WA 98109			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 03/30/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

angiotechpatents@angio.com

Office Action Summary

Application No.

10/065,279

Applicant(s)

LEUNG ET AL.

Examiner

TUAN V. NGUYEN

Art Unit

3731

Period for Reply
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/17/11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58, 60 and 63-140 is/are pending in the application.
- 4a) Of the above claim(s) 37-57 and 63-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 58, 60 and 102-140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 and 16 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-58, 60 and 63-140 are pending in this present application. In previous Office action claims 1-36, 58, 60 and 102-140 were examined and rejected and claims 37-57 and 63-101 were previously withdrawn due to restriction requirement.
2. This Office action is in response to the RCE filed on 02/17/11.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/17/11 has been entered.

Response to Arguments

4. Applicants' arguments filed on 02/17/11 have been fully considered but they are moot in view of new ground of rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. **Claims 1-3, 5-9, 10, 12, 14-21, 23-30, 32-36, 58, 60 and 102-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) in view of Genova et al. (U.S. 7,225,512).**
8. The applied reference, Genova et al. (U.S. 7,225,512), has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or

declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

9. Referring to **claims 1-3**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke further discloses the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines 12-19). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside and the underside of the barb attaches to the suture body along a line that is transverse to the longitudinal axis of the elongate body and is arcuate, and **(2)** the barb cut angle ranging from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees.
 - a. As to point **(1)**, Genova discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body. Genova discloses the advantage of the method is "simplify production equipment; produce a stronger suture; reduce production cycle time by at least a factor of three;

and be easily scalable to smaller diameters" (col. 2, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the barb configuration and manufacturing technique as disclosed by Genova to replace the barb suture as disclosed Buncke so that it too would have the same advantage.

- b. As to point **(2)**, Figures 15 and 16 of Buncke drawings show the barb 98, which created by cutting blade 92, wherein the blade has a sharp cutting edge, a base and an angle. Thus the barbs 98 of Buncke disclose the general condition of the barb cut angle Θ on the suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut angle ranging from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
10. Referring to **claims 10-12**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside and the underside of the barb attaches to the suture body along a line that is transverse to the

longitudinal axis of the elongate body and is arcuate, and (2) the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5.

- a. As to point (1), Genova discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body. Genova discloses the advantage of the method is "simplify production equipment; produce a stronger suture; reduce production cycle time by at least a factor of three; and be easily scalable to smaller diameters" (col. 2, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the barb configuration and manufacturing technique as disclosed by Genova to replace the barb suture as disclosed Buncke so that it too would have the same advantage.
- b. As to point (2), noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines 12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Referring to **claims 19-22**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having an elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside and the underside of the barb attaches to the suture body along a line that is transverse to the longitudinal axis of the elongate body and is arcuate, and **(2)** the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5.
 - a. As to point **(1)**, Genova discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body. Genova discloses the advantage of the method is "simplify production equipment; produce a stronger suture; reduce production cycle time by at least a factor of three; and be easily scalable to smaller diameters" (col. 2, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the barb configuration and manufacturing technique as disclosed by Genova to replace the barb suture as disclosed Buncke so that it too would have the same advantage.

- b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material. (col. 8, lines 12-19). Further, Figures 15 and 16 of Buncke drawings show the barb 98 having a barb cut length, thus the barbs 98 of Buncke disclose the general condition of the barb cut length. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
12. Referring to **claims 28-30**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having an elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside and the underside of the barb attaches to the suture body along a line that is transverse to the longitudinal axis of the elongate body and is arcuate, and **(2)** the barb cut distance

with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5.

- a. As to point (1), Genova discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body. Genova discloses the advantage of the method is "simplify production equipment; produce a stronger suture; reduce production cycle time by at least a factor of three; and be easily scalable to smaller diameters" (col. 2, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the barb configuration and manufacturing technique as disclosed by Genova to replace the barb suture as disclosed Buncke so that it too would have the same advantage.
- b. As to point (2), noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material. (col. 8, lines 12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Referring to **claim 58**, since claim 58 is the combination of claims 1, 10, 19 and 28, Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
14. Referring to **claim 60**, since claim 60 is the combination of claims 1, 10, 19, 28, and a twist cut with a spirality angle α ranging from about 5 degrees to about 25 degrees. Noting that Buncke also disclose the barbs can be positioned in a spiral pattern if desired (col. 9, lines 3-10), Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
15. Referring to **claims 5-8, 14-17, 23-26, and 32-35**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (col. 1, lines 20-25).

16. Referring to **claims 9, 18, 27, and 36**, Buncke discloses the barbs can be on opposed sides of the suture, staggered, and they can be positioned in a spiral pattern if desired (col. 9, lines 3-10).
17. Referring to **claims 102-114**, Buncke discloses the suture 10 has about 100 to 500 microns in diameter (col. 4, lines 55-60), thus Buncke discloses the suture 10 having circular cross-section.
18. **Claims 4, 13, 22, 31 and 115-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and Genova et al. (U.S. 7,225,512) as applied to claims 1, 10, 19, and 28 above and further in view of Ruff (U.S. 5,342,376).**
19. Referring to **Claims 4, 13, 22, and 31**, Buncke/Genova discloses the invention substantially as claimed except for each set having a barb size different from the barb size of the other set. However, Ruff discloses the configuration of barbs 6 and the surface area of the barbs can vary depending upon the tissue in which the barbed suture is used (e.g. if the barbed suture is intended for use in fatty tissue, which is relatively soft, the barbs can be made longer to increase the holding ability in the soft tissue) (col. 4, lines 5-17 and col. 5, lines 2-6). It would have been obvious to one of ordinary skill in the art to design the barbed suture of Buncke/Genova to have at least two sets, wherein each set having a barb size different from the barb size of the other set for the purpose as disclosed by Ruff so that it too would have the same advantage.

20. Referring to **claims 115-140**, Buncke/Genova discloses the invention substantially as claimed except for the cross section of suture body has a non-circular cross section. However, Ruff discloses a non-circular cross section shape (e.g. rectangular or hexagonal cross section) increases the surface area of the suture body and facilitates the formation of the multiple barbs on the suture body (col. 6, lines 18-28). It would have been obvious to one of ordinary skill in the art to incorporate the teaching of Ruff into the suture of Buncke/Genova so that it too would have the same advantage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/TUAN V NGUYEN/
Examiner, Art Unit 3731